



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|---|
| Summary for ARTG Entry: | 311269 | METAGENICS FIBROPLEX MAGACTIVE FOR KIDS |
| ARTG entry for | Medicine Listed | |
| Sponsor | Metagenics (Aust) Pty Ltd | |
| Postal Address | PO Box 675, VIRGINIA BC, QLD, 4014 Australia | |
| ARTG Start Date | 7/11/2018 | |
| Product Category | Medicine | |
| Status | Active | |
| Approval Area | Listed Medicines | |

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1 . METAGENICS FIBROPLEX MAGACTIVE FOR KIDS

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 14/07/2021 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

- Maintain/support energy levels in children
- Maintain/support muscle function in children
- Maintain/support muscle relaxation in children
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in children
- Support healthy stress response in the body in children
- Maintain/support nervous system health in children
- Support healthy emotional/mood balance in children

Indication Requirements

- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- Product presentation must not imply or refer to chronic fatigue syndrome.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

- This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.
- Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.
- If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Pack Size/Poison information

| | |
|------------------|------------------------|
| Pack Size | Poison Schedule |
|------------------|------------------------|

Components

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1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|---|---------------------------|
| acetyl levocarnitine hydrochloride | 16.79 mg/g |
| ascorbic acid | 42.86 mg/g |
| chromium nicotinate | 35.71 microgram/g |
| Equivalent: chromium | 3.57 microgram/g |
| glutamine | 71.43 mg/g |
| magnesium glycinate dihydrate | 428.57 mg/g |
| Equivalent: magnesium | 42.86 mg/g |
| mecobalamin (co-methylcobalamin) | 21.43 microgram/g |
| nicotinamide | 7.14 mg/g |
| pyridoxal 5-phosphate monohydrate | 7.14 mg/g |
| Equivalent: pyridoxine | 4.56 mg/g |
| riboflavin sodium phosphate | 371.95 microgram/g |
| Equivalent: riboflavin | 271.52 microgram/g |
| selenomethionine | 8.93 microgram/g |
| Equivalent: selenium | 3.57 microgram/g |
| taurine | 85.71 mg/g |

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
citric acid
colloidal anhydrous silica
Colour
Flavour
malic acid
monobasic potassium phosphate
Steviol glycosides

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